COMPOSITIONS AND METHODS OF TREATMENT FOR CHRONIC RHINOSINUSITIS

RELATED APPLICATIONS

[0001] The present patent application claims the benefit of the filing date of U.S. Provisional Patent Application No. 62/684,019, filed Jun. 12, 2018, the contents of which is hereby incorporated by reference.

TECHNICAL FIELD

[0002] The present disclosure is generally directed to compositions and methods for modifying the microbiome in the nasal cavity and more specifically directed to compositions and methods for modifying the microbiome in the nasal cavity of subjects having chronic sinusitis and/or asthma.

BACKGROUND

[0003] Chronic rhinosinusitis (CRS) is a chronic inflammatory disease involving the mucosal tissue of the upper airways, including the nose and paranasal sinuses. The inflammatory milieu in patients with CRS is thought to be affected by or even possibly initiated by commensal microbes, pathogens, and their products[1,2] Asthma is a related chronic inflammatory disease of the lower airways that is often comorbid with CRS. Uncontrolled upper airway inflammation in the context of CRS is associated with lower airway T-helper-2-mediated inflammation and recalcitrant asthma, however; the underlying mechanism of this link is rather complicated and currently under investigation. Rhinosinusitis is also linked to increased asthma severity and exacerbation rate. Nevertheless, fundamental questions regarding the mechanisms of chronic mucosal inflammation in CRS and how chronic sinonasal inflammation may affect the lower airways remain unanswered. Considering the likely possibility that microorganisms extant in the upper airways will be aspirated into the lungs, studies of the sinonasal microbiome in the context of lung health appear to be worthwhile. Microbiome studies provide important knowledge about both commensal and pathogenic microbes residing in the airways.[2]

[0004] To date, only a few studies have evaluated the nasal microbiome in patients with CRS. There has been a lack of consistency in these studies in terms of both abundance and the α-diversity indices of bacteria.2 Thus far, all previous studies have evaluated the microbiome in terms of its α-diversity (ie, richness) and relative abundance (RA) in each operational taxonomic unit (OTU) that alone do not provide any in-depth information on the potential functional effect of the nasal microbiota. The present disclosure evaluates sinonasal bacterial communities by using predictive functional profiling and identifies aspects of the microbiome for modulation to treat CRS and/or asthma.

SUMMARY

[0005] In some aspects, methods for treating sinusitis in a subject are provided. The methods include administering to the subject an effective amount of a composition that stimulates growth or activity of a genus of bacteria that is decreased relative to a control subject not having sinusitis and/or inhibiting growth or activity of a genus of bacteria that is increased relative to the control subject.

[0006] In other aspects, compositions for treating sinusitis in a subject are provided. Compositions include a bacterial composition including bacteria from the genus *Corynebacterium* and/or the genus *Peptoniphilus*

DETAILED DESCRIPTION

Definitions

[0007] For the purpose of promoting an understanding of the principles of the invention, reference will now be made to embodiments, some of which are illustrated in the drawings, and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any alterations and further modifications in the described embodiments, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the invention relates. In the discussions that follow, a number of potential features or selections of assay methods, methods of analysis, or other aspects, are disclosed. It is to be understood that each such disclosed feature or features can be combined with the generalized features discussed, to form a disclosed embodiment of the present invention.

[0008] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention pertains. In case of conflict, the present document, including definitions, will control. Preferred methods and materials are described below, although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention.

[0009] The uses of the terms "a" and "an" and "the" and similar references in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as", "for example") provided herein, is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

[0010] As used herein, "microbiome" refers to the population of microorganisms that are present in a particular environment, such as the nasal cavity, the gut or digestive system, the urogenital tract, the mouth, the oral cavity, and the like. A microbiome is a microbial population defined by the diversity as well as the relative amounts of bacteria that compose a particular microbiome.

[0011] The term "therapeutic effect" as used herein means an effect which induces, ameliorates or otherwise causes an improvement in the pathological symptoms, disease progression or physiological conditions associated with a disorder, for example sinusitis, such as chronic rhinosinusitis or